

REMARKS

Claims 1-18, 22-45 and 48-54 are currently pending. Claims 2-18, 22-45, and 48-54 have been withdrawn, leaving claim 1 under examination.

Claim 1 has been amended herein. The amendment is fully supported by the specification and introduces no new matter.

Claim Objections

Claim 1 has been objected to for the alleged misspelling of the word lethal as letal on line 8. Applicant's electronic copy of the specification, as filed, and the preliminary amendment, as filed, do not have the word "lethal" or "letal" on line 8, nor is the word "lethal" misspelled anywhere in claim 1. Applicant respectfully requests the Examiner reconsider the objection as Applicant is presently unable to locate the error in order make the required correction.

The Claim is Sufficiently Definite

Claim 1 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for recitation of the expression "said protein" because the claim comprises a lethal protein and a GAS1 protein. Applicants respectfully traverse. Proper grammatical construction of the claim reveals that the recitation cannot properly refer to "said Gas1 protein" whose function or expression is inhibited in the first clause of step (b) because the clause "wherein said protein" does not modify that clause as it is separated by the semicolon separating the step (b) from step (c). It is clear from the paragraphing of the claim that the expression "wherein said protein" can only modify an otherwise lethal protein in the preamble, or alternatively read of step (c). Accordingly, in either case the claim as written is sufficiently clear to apprise the skilled artisan of what Applicant is claiming because in either case the "wherein said protein" modifies the "otherwise lethal protein". Although Applicant does not concur in the rejection, in an effort to advance prosecution the claim has been amended to even more clearly reflect to which protein the clause refers. The rejection is accordingly moot, and the rejection under 35 U.S.C. § 112, second paragraph must be withdrawn. Reconsideration is respectfully requested in view of the foregoing.

Claim 1 also stands rejected under 35 U.S.C. § 112, second paragraph as allegedly omitting an essential step(s) amounting to a gap between the steps. Applicant respectfully traverses the rejection. No essential step is omitted and rejection under 35 U.S.C. § 112, second paragraph is not appropriate here. *MPEP 2172.01* states:

2172.01 Unclaimed Essential Matter [R-1]

A claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may be rejected under 35 U.S.C. 112, first paragraph, as not enabling. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). *See also MPEP § 2164.08(c)*. Such essential matter may include missing elements, steps or necessary structural cooperative relationships of elements described by the applicant(s) as necessary to practice the invention.

In addition, a claim which fails to interrelate essential elements of the invention as defined by applicant(s) in the specification may be rejected under 35 U.S.C. 112, second paragraph, for failure to point out and distinctly claim the invention. *See In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976); *In re Collier*, 397 F.2d 1003, 158 USPQ 266 (CCPA 1968). >But see *Ex parte Nolden*, 149 USPQ 378, 380 (Bd. Pat. App. 1965) ("[I]t is not essential to a patentable combination that there be interdependency between the elements of the claimed device or that all the elements operate concurrently toward the desired result"); *Ex parte Huber*, 148 USPQ 447, 448-49 (Bd. Pat. App. 1965) (A claim does not necessarily fail to comply with 35 U.S.C. 112, second paragraph where the various elements do not function simultaneously, are not directly functionally related, do not directly intercooperate, and/or serve independent purposes.)

Applicant respectfully asserts that if the Office Action is alleging that a step is *missing* it appears from the above that the rejection must be based on 35 U.S.C. § 112, first paragraph, and not on 35 U.S.C. § 112, second paragraph. However, as the Office Action concedes, the step of inhibiting is plainly present in the claim as step (b). Applicant thus respectfully asserts that here, there is no gap or missing step. Further, an exact method of inhibiting the function or expression of the GAS1 polypeptides is not required under 35 U.S.C. § 112, second paragraph. Claim is definite in requiring an inhibition step which the skilled artisan would understand from the plain language of the claim, and especially in view of the teachings of the specification.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

The Claim is Adequately Described

Claim 1 stands rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement because it encompasses Gas1 functional equivalents, derivatives, or bioprecursors. Claim 1 as amended does not recite functional equivalents, derivatives, or bioprecursors. The claim, directed to Gas1 polypeptides as now claimed, is adequately described and the Applicant was clearly in possession of the claimed method. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Claim 1 also stands rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to satisfy the written description requirement because it encompasses “otherwise lethal proteins” which are not adequately described. The claim as amended is limited to a specific group of proteins whose structures are well known to those of skill in the art. Support for the amendment may be found on page 32, lines 10-31. The Applicant was in clearly in possession of the nucleic acid sequences encoding such proteins to the extent they were known to skilled artisans at the time of filing, particularly where, as here, there was clearly established relationship between structure and function for these well understood proteins. Applicant need not disclose that which is well known. Thus, the Applicant was in possession at the time of filing of what is now claimed. Accordingly, Applicant respectfully requests reconsideration and that the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, with respect to “other lethal protein” be withdrawn.

Claim 1 stand further rejected under 35 U.S.C. § 112, first paragraph allegedly because the claim encompasses “any protein that is in the Gas1 signal transduction pathway”. The claim as amended no longer recites or refers to “any protein that is in the Gas1 signal transduction pathway” and accordingly the grounds of the rejection are obviated. Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph with respect to “any protein that is in the Gas1 signal transduction pathway.”

Conclusion:

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Applicant respectfully asserts that this amendment and the associated remarks are fully responsive to the outstanding Office Action. The claim is now in condition for allowance. Applicant earnestly solicits an early and favorable notice to that effect.

Respectfully submitted,

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